EXHIBIT 2

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP., Plaintiff, v. BLUEWILLOW BIOLOGICS, INC., ROBIN ROE 1 through 10, gender neutral fictitious names, and ABC CORPORATION 1 through 10 (fictitious names). Defendants.	Case No. 2:21-cv-10312-SJM-RSW Hon. Stephen J. Murphy, III

DECLARATION OF MANSOOR M. AMIJI, PH.D. IN SUPPORT OF BLUEWILLOW'S CLAIM CONSTRUCTION BRIEF

I, Dr. Mansoor M. Amiji, declare as follows:

1. My name is Mansoor M. Amiji. I have been retained as an expert witness on behalf of BlueWillow Biologics, Inc. ("BlueWillow") for the above-captioned matter. I am being compensated for my time in connection with this litigation at my standard consulting rate of $900 per hour. My compensation is not affected by the outcome of this matter.

2. I have been informed that Trutek has accused BlueWillow of infringing claims 1, 2, 6 and 7 of U.S. Patent No. 8,163,802 ("the '802 Patent") (attached as Exhibit 1) and have been asked to provide my opinion and analysis regarding whether the asserted claims reasonably inform a person of ordinary skill in the art as to the scope of the claimed invention. My opinions and analysis set forth in this declaration are based upon my analysis of the '802 Patent, the prosecution history, the state of the art at the time of the invention, as well as my knowledge and experience in the relevant field.

3. For the reasons explained below, it is my opinion that several elements of the asserted claims, including "electrostatically inhibiting," "electrostatically attracting," "adequate impermeability," and "render[s] said particulate matter harmless," do not reasonably inform a person of ordinary skill in the art as to the scope of the claimed invention of asserted claims 1, 2, 6 and 7 of the '802 Patent.

I. QUALIFICATIONS AND EXPERIENCE

4. I am an expert in the field of pharmaceutical sciences and drug formulation development and characterization. Specifically, I specialize in drug formulation development and targeted delivery of therapeutics, and I have been an expert in this field since prior to July 7, 2008. I have relied upon my training, knowledge, and experience in the relevant art to form my opinions.

5. In 1988, I graduated with honors from Northeastern University and received a Bachelor of Science degree in Pharmacy and became a Registered Pharmacist in Massachusetts. In 1992, I received a Ph.D. in Pharmaceutical Science/Pharmaceutics from the School of Pharmacy and Pharmaceutical Sciences at Purdue University, under the supervision of Professor Kinam Park. My dissertation focused on biomaterials and water-soluble polymers. During my graduate studies at Purdue University, I took several pharmaceutics courses and had hands-on training in pharmaceutical formulation development and characterization.

6. After receiving my Ph.D. in 1992, I worked as a Senior Research Scientist for Columbia Research Laboratories (CRL) in Madison, Wisconsin. At CRL, I worked on polymeric delivery systems for various types of therapeutic agents, including those administered topically to skin and mucosal surfaces.

7. I am currently the University Distinguished Professor and Professor of Pharmaceutical Sciences in the School of Pharmacy, Bouve College of Health Sciences at Northeastern University in Boston, Massachusetts. I am also jointly appointed as a Professor of Chemical Engineering in the College of Engineering at Northeastern University. I am also currently an Affiliate Faculty Member in the Department of Biomedical Engineering at Northeastern University. I have taught and carried out research in pharmaceutical sciences at Northeastern University since 1993, and from 2010 to 2016, I served as the Chairman of the Department of Pharmaceutical Sciences. In 2000, I was a Visiting Research Scholar in the Department of Chemical Engineering at the Massachusetts Institute of Technology (MIT) in Cambridge, Massachusetts, in the laboratory of Professor Robert Langer.

8. As a tenured faculty member at Northeastern University, I have over 29 years of experience in teaching drug formulations to both graduate and undergraduate students. In theory and laboratory courses that I have taught and continue to teach, I extensively cover the manufacturing and composition of pharmaceutical formulations, delivery systems and pharmacokinetics. I also serve as a consultant to several pharmaceutical, biotechnology, and medical device companies regarding product development and drug delivery.

9. I lecture extensively on various topics at the leading edge of modern pharmaceutical sciences, and I regularly attend numerous worldwide

pharmaceutical conferences. I have been an invited speaker at national and international scientific conferences.

10. Over the course of my career I have published extensively and am ranked as a Thompson-Reuters Highly Cited (top 1%) author in Pharmacology and Toxicology. I have coauthored over 60 book chapters and more than 350 peer reviewed scientific articles. I am also an inventor on several issued United States patents. The topics of these materials including the design and development of pharmaceutical dosage forms, pharmacokinetics, drug metabolism, dose delivery and controlled research systems and the use/formulation of related excipients and methods. I have been involved in and consulted on multiple projects over the years both in industry and academia about the aforementioned topics. To that end, I have taught courses in pharmaceutics; drug design, evaluation, and development; dosage forms; and pharmacokinetics.

11. I have served as a grant reviewer for the National Institutes of Health, the Department of Defense, the United States Department of Agriculture, and the American Chemical Society. I am a member of several professional and industrial societies, including the American Association of Pharmaceutical Sciences (AAPS) and the Controlled Release Society (CRS), and have participated as a reviewer for more than 50 scientific journals.

12. I have also received a number of professional awards and honors, including the Nano Science and Technology Institute (NSTI) Fellowship Award for Outstanding Contributions towards the Advancement in Nanotechnology, Microtechnology, and Biotechnology in 2006; a Fellowship and Meritorious Manuscript Award from the AAPS in 2007; the Tsuneji Nagai Award from the CRS in 2012; the Northeastern University School of Pharmacy Distinguished Alumni Award in 2016; and Purdue University College of Pharmacy Distinguished Alumni Award in 2019. Over the course of my career, I have advised numerous post-doctoral associates, doctoral students, master's students, visiting scientists, and research fellows.

13. I am a founder and scientific advisor to many pharmaceutical companies, including Nemucore Medical Innovations and Targagenix, Inc., which have licensed our patents on lipid-based drug delivery systems and is in the process of developing commercial products.

14. I was appointed as a Fellow of the American Association of Pharmaceutical Scientists (AAPS) in 2007 and served as a long-term member of the Association. I am also a Fellow of the Controlled Release Society (CRS) since 2014 and serve on the Scientific Advisory Board of the CRS. I have also served as a permanent member of the National Institutes of Health's grant review panel and many other public funding agencies in the U.S. and across the world. I am an Editor

of the journal Drug Delivery and Translational Research and Associate Editor of several peer-reviewed journals and on the editorial board of about a half dozen other scientific journals.

15. Additional details concerning my background, training and experience are contained in my current *Curriculum Vitae*, attached as Exhibit 2.

16. Based on my education, training, and experience, including my research expertise in pharmaceutical product development and drug formulation development of over 29 years, including in the July 7, 2008 time frame, I am qualified to provide technical analysis and opinions regarding the subject matter of this case and the ’802 Patent.

II. UNDERSTANDING OF CLAIM CONSTRUCTION PRINICIPLES

17. I am not an attorney. For purposes of this declaration, I have been informed about certain aspects of the law that are relevant to my opinions, as described below.

18. I have been informed that the issue of claim indefiniteness may be considered during the claim construction stage. I have further been informed that patent claims are invalid for indefiniteness if the “claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.”

III. OVERVIEW OF THE '802 PATENT

19. The '802 Patent is titled "Electrostatically Charged Multi-acting Nasal Application, Product, and Method." The named inventor is Ashok Wahi. The named assignee of the '802 Patent is Trutek Corp. ("Trutek").

20. The '802 Patent issued on April 24, 2012, from U.S. Application No. 12/467,271 (the "'271 Application") filed on May 16, 2009. The '802 Patent claims priority to Provisional Application No. 61/078,478, filed on July 7, 2008.

21. As described in the Abstract of the '802 Patent, the purported invention is one of "reducing the risk of inhalation of harmful substances by applying a formulation," which "when applied creates an electrostatic field having a charge." '802 Patent, Abstract. More specifically, the asserted claims recite a method and formulation for "electrostatically inhibiting harmful particulate matter from infecting an individual" wherein "a formulation is applied to skin or tissue of nasal passages of the individual in a thin film" and "electrostatically attracting the particulate matter to the thin film." '802 Patent, Claim 1.

22. Asserted claims 1, 2, 6 and 7 of the '802 Patent are listed below:

> 1. A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation where a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:
>
> a) electrostatically attracting the particulate matter to the thin film;

b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,

c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

2. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:

a) electrostatically attracts the particulate matter to the thin film;

b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,

c) inactivates the particulate matter and renders said particulate matter harmless.

6. The formulation of claim 2 wherein the at least one cationic agent is Benzalkonium Chloride.

7. The formulation of claim 2 wherein the at least one cationic agent is Benzalkonium Chloride or Lysine HCL.

IV. THE PERSON OF ORDINARY SKILL IN THE ART

23. For purposes of this declaration, I assume that the ‘802 Patent is entitled to the July 7, 2008 priority date.

24. I understand that there are multiple factors relevant to determining the level of ordinary skill in the pertinent art, including the educational level of active workers in the field at the time of the alleged invention, the sophistication

of the technology, the type of problems encountered in the art, and the prior art solutions to those problems.

25. In determining the characteristics of a hypothetical person of ordinary skill in the art of the ’802 Patent at the time of the claimed invention, I considered several things, including the type of problems encountered in this field, and the rapidity with which innovations were made. I also considered the sophistication of the technology involved, and the educational background and experience of those actively working in the field, and the level of education that would be necessary to understand the ’802 Patent. Finally, I placed myself back in the relevant period of time and considered the state of the art and the level of skill of the persons working in this field at that time.

26. It is my opinion that the art of the subject matter of the ’802 Patent is a pharmaceutical formulation. Based on the materials I have considered, my own experience, and the knowledge required to design pharmaceutical formulation including the use of excipients, I came to the conclusion that the characteristics of a person of ordinary skill in the art of the ’802 Patent would be someone who had at least an M.S. degree in chemical engineering, pharmaceutical sciences, or a related field (or the equivalent) with several years of experience with pharmaceutical formulation. Also, a person of ordinary skill in the art may have worked as part of a multidisciplinary team— including a chemical engineer,

microbiologist, or polymer chemist—and drawn upon not only his or her own skills, but also taken advantage of certain specialized skills of others on the team, *e.g.*, to solve a given problem.

27. Based on my education, training, and experience, including my research expertise in pharmaceutical product development and drug formulation development of over 29 years, I satisfied the above requirements of a person of ordinary skill in the art as of the July 7, 2008 time frame.

28. I understand that Trutek's experts disagree with my opinion regarding the level of a person of ordinary skill in the art as it applies to the subject matter of the '802 Patent. More specifically, I understand Trutek's experts to opine that the person of ordinary skill in the art would have a lower level of skill, and "should be able to create the formulations described in the patent" but "need not possess an advanced degree. Further, he does not even need to possess an undergraduate degree. He must be a technician with several years of experience as a formulator. The key requirement is his acquired experience necessary to create a wide variety of formulations from the class of ingredients disclosed in the '802 Patent."

29. I disagree with the positions taken by Trutek's experts on the level of ordinary skill in the art of the '802 Patent. In my opinion, it is not enough to simply possess undetermined years of experience in creating "a wide variety of

formulations from the class of ingredients disclosed in the '802 Patent" and the ability to read the patent and make the various formulations described in the patent. As explained above and in more detail below, the claimed invention of the '802 Patent is not directed merely to making and using the various formulations described in the '802 Patent specification, but rather, specific formulations that are capable of "electrostatically inhibiting harmful particulate matter from infecting an individual" wherein the "formulation is applied to skin or tissue of nasal passages of the individual in a thin film" and "electrostatically attracting the particulate matter to the thin film." '802 Patent, Claim 1. A person who simply possesses the experience and ability to read the '802 Patent and make certain formulations from the ingredients listed in the '802 Patent would not necessarily have the requisite level of skill to assess whether any such formulations are sufficient to actually achieve the result described in the asserted claims, including "electrostatically attracting" and "electrostatically inhibiting harmful particulate matter from infecting an individual."

V. THE ASSERTED CLAIMS DO NOT INFORM A PERSON OF ORDINARY SKILL IN THE ART WITH REASONABLE CERTAINTY OF THE SCOPE OF THE CLAIMED INVENTION

30. In my opinion, based on my review of the '802 Patent, the prosecution history, and my experience and knowledge in the relevant field of art, several elements of the asserted claims, including "electrostatically inhibiting,"

"electrostatically attracting," "adequate impermeability," and "render[s] said particulate matter harmless" do not reasonably inform a person skilled in the art about the scope of the claimed invention of asserted claims 1, 2, 6 and 7 of the '802 Patent. In reaching this opinion, I have primarily applied my understanding of the level of ordinary skill in the art as described above, but have also considered the question from the differing perspective offered by Trutek's experts.

31. Each of these claim elements incorporate relative and subjective terms, and the specification of the '802 Patent does not provide any information that a person of ordinary skill in the art would need to assess with reasonable certainty the scope of potential formulations that are capable of achieving the claimed effect of "electrostatically inhibiting," "electrostatically attracting," providing "adequate impermeability," and "render[ing] said particulate matter harmless."

32. The '802 Patent includes ten separate tables, each with numerous formulations and compounds that are variable. The '802 Patent further states:

> All of the formulations described in TABLE 1-10 representing various embodiments of the Present Invention operate in the manner that was disclosed herein. The same results may be achieved by varying the percentages for the active and inactive ingredients. Varying the percentages for the active ingredients affects the potency of the formulation. Varying the percentages for the inactive ingredients affects the consistency of the formulation. The desired results may be achieved by varying the ingredients and their amounts by those skilled in the art without undue experimentation.

'802 Patent at 10:7-17.

33. While a person skilled in the art reading the '802 Patent would understand that the specification provides a laundry list of possible formulations, the patent specification does not include any specific examples, data, or test results for any of the formulations demonstrating that they work by "electrostatically attracting" particulate matter to a thin film applied to the nasal passages and holding the particulate matter in place through adhesion to the thin film in order to "electrostatically inhibit" such harmful particulate matter from infecting an individual. Likewise, the '802 Patent does not provide any guidance to exemplify a formulation that achieves the claimed goal of "electrostatically inhibiting harmful particulate matter from infecting an individual." Additionally, there is nothing in the claimed composition that makes the ingredients selective to "harmful particulate matter" as opposed to other negatively-charged particles, such as dust particles.

34. Nor does the ’802 Patent provide any guidance as to what types of tests should be conducted in order to determine whether a particular formulation would “operate in the manner” disclosed, e.g., by “electrostatically attracting” and “electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation.”

35. Likewise, the ’802 Patent does not provide any examples or guidance as to how the percentages of components can be varied while still achieving “the same results.” Indeed, the ’802 Patent acknowledges that varying the percentages of the ingredients can affect the potency of the formulation and the consistency of the formulation. Both of these attributes would impact the adhesive, film forming, and electrostatic properties of the formulation, i.e., the ability of the formulation to “electrostatically attract” and “electrostatically inhibit” harmful particulate matter, in addition to the ability of the formulation to “render said particulate material harmless” and the claimed “adequate impermeability” of the thin film created by the formulation upon application.

36. With respect to the relative claim terms of “electrostatically inhibiting” and “electrostatically attracting,” the ’802 Patent also fails to provide any information concerning the specific charge density or other quantitative parameters that will be needed to create the electrostatic field, what magnitude of electrostatic field is necessary to attract oppositely charged contaminants, how far

the electrostatic field needs to be from the application surface, how much of the product must be applied to be effective, or how long the composition must stay on the skin to be effective. As such, a person of ordinary skill in the art would not be able to assess with reasonable certainty whether a particular formulation falls within the scope of the claim such that it is capable of "electrostatically attracting" and "electrostatically inhibiting" harmful particulate matter from infecting an individual.

37. In addition, the claimed element of providing "adequate impermeability" to the thin film formed upon application of the formulation to the skin is also relative and subjective. The term "adequate" alone does not inform the person of ordinary skill in the art as to how impermeable the thin film must be, or even the purpose for having a thin film with "adequate impermeability." Nor does the '802 Patent provide the person of ordinary skill in the art with any information as to what level of impermeability is required and for what purpose, what level of impermeability is required for each harmful pathogen, or how to test for such impermeability, rendering the question of whether the formulation creates a thin film of "adequate impermeability" purely subjective within the viewpoint of the person of ordinary skill in the art.

38. The claim element of "render[ing] said particulate matter harmless" is likewise both relative and subjective. As explained above, the '802 Patent

acknowledges that varying the percentages of the ingredients can affect the potency and consistency of the formulation. Both of these attributes would impact the ability of the formulation to "render said particulate material harmless." In addition, while the '802 Patent explains that the "electrostatically charged nasal applications products are used to hold the contaminants . . . outside the body and render them harmless," the patent does not explain how much of the harmful particulate matter must be "held" in order to render it "harmless." Additionally, the properties of individual pathogen particles vary, and there is no specific guidance on what type of composition or dosage will be needed for each type of pathogen or use. Nor does the '802 Patent provide the person of ordinary skill in the art with any information as to how to test, measure, or determine with reasonable certainty whether a particular formulation is capable of "render[ing] said particulate matter harmless."

39. Finally, in my opinion, if one were to apply the (much lower) definition of the person of ordinary skill in the art advocated by Trutek's experts, such person would have even more difficulty in ascertaining with reasonable certainty the scope of the claimed invention, particularly in view of the lack of teaching and guidance in the '802 Patent as to how to make and use the claimed invention. Trutek's experts have opined that the person of ordinary skill in the art need only have a certain amount of experience in in creating "a wide variety of

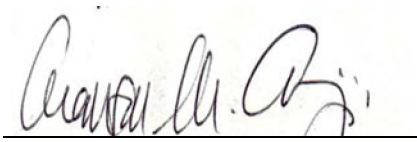
formulations from the class of ingredients disclosed in the '802 Patent" and the ability to read the patent and make the various formulations described in the patent.

40. As explained above, the claimed invention is directed to formulations that are capable of "electrostatically inhibiting harmful particulate matter from infecting an individual." The '802 Patent, however, does not provide any guidance as to the specific charge density or other quantitative parameters that will be needed to create the electrostatic field, what magnitude of electrostatic field is necessary to attract oppositely charged contaminants, how far the electrostatic field needs to be from the application surface, how much of the product must be applied to be effective, or how long the composition must stay on the skin to be effective. Likewise, the '802 Patent does not provide any guidance as to what level of impermeability is required to provide "adequate impermeability" and for what purpose. In my opinion, a person who simply possesses the experience and ability to read and make certain formulations from the ingredients listed in the '802 Patent would not be able to assess with reasonable certainty whether any such formulations are sufficient to "electrostatically attract" and "electrostatically inhibit" harmful particulate matter from infecting an individual, provide "adequate impermeability" and/or "render said particulate matter harmless," particularly in view of the fact that the '802 Patent provides no guidance or instruction as to how to even test for these claimed attributes.

41. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: September 8, 2022

Respectfully submitted,



Mansoor M. Amiji, Ph.D.